UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

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PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, et al., Plaintiff(s), v. BRIAN SANDOVAL, et al., Defendant(s).	Case No. 2:17-CV-2315 JCM (CWH) ORDER

Presently before the court is plaintiffs Pharmaceutical Research and Manufacturers of America ("PRMA") and Biotechnology Innovation Organization's ("BIO") motion for a temporary restraining order.[1] (ECF No. 26). Plaintiffs request that this court require defendants Brian Sandoval (in his official capacity as Governor of Nevada) and Richard Whitley (in his official capacity as Director of the Nevada Department of Health and Human Services, or "NDHHS") "to immediately cease and desist all action implementing or enforcing Sections 3.6–4, 4.3, 6, 7, 8, 9, and all related sections or subsections of Nevada Senate Bill No. 539." (ECF No. 26 at 2).

I. Facts

On June 5, 2017, The Nevada Senate and State Assembly both passed SB 539 ("SB 539"). As relevant to this case, the bill creates a reporting scheme for information related to diabetes drugs. The bill requires NDDHS to promulgate a list of prescription drugs essential for the treatment of diabetes by February 1 of each year. Thereafter, the manufacturers of drugs on the

[1] Plaintiffs have also filed a motion for preliminary injunction. (ECF No. 27).

list must provide NDHHS with a report by April 1 of each year.[2] The report must contain cost, pricing, profit, coupon, rebate, and related metrics for the manufacturer's drug, along with any other "information prescribed by regulation . . . for the purpose of analyzing the cost of prescription drugs . . . on the list."[3] SB 539 § 3.8. On or before June 1 of each year, NDHHS shall compile a report summarizing certain manufacturer disclosures. SB 539 § 4.3. Pursuant to Section 28, subsection 3,

> Sections 1 to 6.5, inclusive, 7.5, 8, 9, and 26.6 of this act become effective upon passage and approval for the purpose of adopting regulations and performing any other administrative tasks that are necessary to carry out the provisions of this act and on October 1, 2017, for all other purposes.

SB 539 § 28.

Section 26.9 of the bill alters the report deadlines for the first reporting period. SB 539 § 26.9. On or before November 1, 2017, NDHHS shall place on its website the initial list of drugs essential to the treatment of diabetes.[4] *Id.* On or before July 1, 2018, the manufacturers shall submit their first reports pursuant to section 3.6. *Id.* On or before September 1, 2018, NDHHS shall compile its first report pursuant to section 4.3. *Id.*

II. Legal Standard

Under Federal Rule of Civil Procedure 65, a court may issue a temporary restraining order when the moving party provides specific facts showing that immediate and irreparable injury, loss, or damage will result before the adverse party's opposition to a motion for preliminary injunction can be heard. Fed. R. Civ. P. 65. "Injunctive relief is an extraordinary remedy and it will not be granted absent a showing of probable success on the merits and the possibility of irreparable injury should it not be granted." *Shelton v. Nat'l Collegiate Athletic Assoc.*, 539 F.2d 1197, 1199 (9th Cir. 1976).

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[2] Other provisions of the bill impose reporting requirements on certain pharmaceutical sales representatives, non-profit organizations, and other entities. *See, e.g.*, SB 539 §§ 4.6, 4.9.

[3] The bill specifically exempts this information from trade secret protection. SB 539 § 9.

[4] Plaintiffs represent that NDHHS plans to publish its initial list on October 15, 2017. (ECF No. 26 at 11). NDHHS has already published a draft list. (ECF No. 26-4).

III. Discussion

Plaintiffs assert that the disclosure of information required by section 3.6 of the act, and its subsequent publication as required by section 4.3, impermissibly infringes upon plaintiffs' patent and trade secret protections, constitutes a taking of property without just compensation, and violates the dormant commerce clause. Plaintiffs' motion states that not only must a TRO issue as soon as possible, but also that plaintiffs would like to be heard on their motion for preliminary injunction prior to October 1, 2017. Plaintiffs claim "[t]he challenged provisions of SB 539 become effective on October 1, 2017, and officially strip affected manufacturers of trade-secret protection for their confidential data as soon as the department publishes its list of 'essential' diabetes drugs . . . ." (ECF No. 26 at 31). Plaintiffs further state that their members must "immediately reassess the risks and returns of their investments in diabetes therapies." *Id.*

Plaintiffs' motion for a TRO does not satisfy the requirements of Federal Rule of Civil Procedure 65(b)(1). Plaintiffs have not shown that "immediate and irreparable injury, loss or damage will result . . . before the adverse party can be heard in opposition." F.R.C.P. 65(b)(1)(A). The bill became effective for purposes of promulgating regulations on June 15, 2017 (the date it was signed), SB 539 § 28, and the department has already published a proposed list of essential diabetes drugs. (ECF No. 26-4). Further, plaintiffs first round of disclosures to NDHHS are not due until July 1, 2018. SB 539 § 26.9. Plaintiffs have not demonstrated that any additional or irreparable harm will accrue on either October 1, 2017, or on October 15, 2017. Per Federal Rule of Civil Procedure 65, defendants must be afforded time to respond to plaintiffs' motion. *See* F.R.C.P 65(a) & (b)(1)(A).

IV. Conclusion

Plaintiffs have not shown this court that *ex parte* relief is warranted on these facts. The court will therefore deny plaintiffs' motion for a temporary restraining order (ECF No. 26), and will set a schedule for consideration of plaintiffs' motion for preliminary injunction (ECF No. 27).

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Accordingly,

IT IS HEREBY ORDERED, ADJUDGED, and DECREED that plaintiffs' motion for a temporary restraining order (ECF No. 26) be, and the same hereby is, DENIED.

IT IS FURTHER ORDERED that the briefing schedule regarding plaintiffs' motion for preliminary injunction (ECF No. 27) shall proceed as follows: defendants must file their reply to plaintiffs' motion on or before September 27, 2017. Plaintiffs will thereafter have fourteen (14) days to file a reply.

IT IS FURTHER ORDERED that a preliminary injunction hearing is set for October 17, 2017, at 11:00 a.m. in courtroom 6A.

DATED September 14, 2017.

UNITED STATES DISTRICT JUDGE